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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,876	06/01/2001	Jean-Rene Authelin	FI5028-US-CNT	2065

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EXAMINER

JOYNES, ROBERT M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/24/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/871,876

Applicant(s)

AUTHELIN ET AL.

Examiner

Robert M. Joynes

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-18 is/are pending in the application.
- 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

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DETAILED ACTION

Receipt is acknowledged of applicants' Amendment filed on February 10, 2003 and Information Disclosure Statement filed on March 14, 2003.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Jinks (US 4810488). Jinks teaches a crystalline material with a reduced particle size of 2 to 5 microns (Col. 6, Claims 6-10). The material is an anti-inflammatory steroid (Col. 6, Claims 6-10; Col. 1, lines 10-24). This teaching anticipated Claims 12 and 13.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jinks. The teachings of Jinks are discussed above. Jinks does not teach the exact particle sizes to have a median particle size of 1 or 2 microns. Jinks does teach the particle range to be below 10 microns and preferably 2 to 5 microns.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the particle size of the steroid to achieve a mean particle size of 1 or 2 microns. The active agent is micronized using a fluid energy mill (Col. 3, Examples 1 and 2).

One of ordinary skill in the art would have been motivated to do this prepare an active agent to be implemented in an aerosol formulation for inhalation into the human bronchial system.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weishaupt et al. (US 3897010) in view of Hagen et al. (US 4767612) alone, or further in view of Capelle, Jr. et al. (US 6145765).

The Weishaupt reference teaches a method of milling material wherein a fluid energy mill is employed to micronize the material wherein the fluid is an inert gas at low temperature (Col. 2, lines 50-65; Col. 4, lines 19-34). The temperature of the fluid lies in a cryogenic range or a range of the liquefaction temperatures of the inert gas used in the method (Col. 4, lines 19-34). The purpose of the low temperature is to bring

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the milling material to a low temperature to embrittle the material to facilitate pulverization in the fluid energy mill (Col. 2, line 66 – Col. 3, line 17). The temperature of the fluid is reduced to a point such that the material to be milled is no longer plastically or elastically viscous but ruptures readily upon impact with a surface or another particle (Col. 2, line 66 – Col. 3, line 17).

Weishaupt does not expressly teach that the material to be milled is triamcinolone acetonide. The reference further does not expressly teach the inert gas to be helium but rather implicitly teaches the gas to an inert gas, which encompasses helium gas.

The Hagen reference teaches the micronization of triamcinolone acetonide in a fluid energy mill. The particle size range of the micronized triamcinolone acetonide is from 1 to 5 microns (Col. 2, lines 55-59).

While the reference does not teach the complete temperature range, differences in temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to mill triamcinolone acetonide in a fluid energy mill at low temperatures to a mean particle size of 2 microns.

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One of ordinary skill in the art would have been motivated to do this to provide a method that embrittles the milled material to be comminuted, which results in a substantial increase in the throughput of the apparatus for a given energy and in turn provides a substantial increase in efficiency.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Further, the Capelle, Jr. reference teaches that the inert gas used as the fluid for a fluid energy mill can be helium (Col. 5, lines 20-31).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to incorporate helium as the fluid in the fluid energy mill.

One of ordinary skill in the art would have been motivated to do this to choose a gas that is compatible with the material being processed and does not degrade the material upon contact with the fluid (Capelle, Jr., Col. 5, lines 20-31).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed February 10, 2003 have been fully considered but they are not persuasive. Applicants argue that the prior art fails to teach or suggest a method of milling wherein a highly crystalline product or, in other words, a product that contains substantially no amorphous content wherein the median particle size of the product is 1 or 2 microns.

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It is the position of the Examiner that the prior art does teach the method of milling a product to prepare a crystalline product wherein the particle size is from 2 to 5 microns. Further, the limitations of high crystallinity and particle size do not appear in the independent claims and are recited dependent claims.

Jinks teaches a method of milling material to prepare crystalline products that has a particle size below 10 microns, preferably 2 to 5 microns. Therefore, Jinks anticipates Claims 12 and 13 that recite a crystalline material that has substantially no amorphous content and a median particle size of less than 2 microns. The material produced by Jinks is crystalline and has a particle size of 2 to 5 microns preferably but generally below 10 microns. These teachings anticipate the limitations of the instant claims.

Further, the rejection of Claim 1-16 based on Weishaupt, Hagen and Capelle is maintained. The primary reference does not disclose the exact particle size but is again teachings the method of the instant claims. A fluid energy mill is used in the presence of low temperature inert gases to prepare comminuted or pulverized particles. Hagen teaches that triamcinolone acetonide can be micronized using a fluid energy mill to a particle size of 1 to 5 microns. Capelle teaches that a known inert gas for fluid energy mills is helium. At the time the invention was made it would have been obvious to use a fluid energy mill to produce micronized particles of triamcinolone acetonide in a helium environment at low temperatures. The limitations applicants rely on for their arguments are not recited in the independent claims; therefore, the Examiner fails to see the criticality in such limitations when the prior art teaches the method of the instant claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
July 22, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
COMMUNICATIONS CENTER 1600